

---

# VACCINE INFORMATION STATEMENTS

## What You Need to Know

---

Who needs to use VISs	Record keeping requirements
When they should be used	Frequently Asked Questions
Who should get them	Applicable sections of the law
Where to find them	VIS Instruction Sheet
Translations available	Copies of Current VISs

---

**November, 2003**



**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION**

---

## **WHAT** is a Vaccine Information Statement?

Vaccine Information Statements (VISs) are one-page (two-sided) information sheets, produced by CDC. Their purpose is to inform vaccine recipients of the benefits and risks of vaccines. The appropriate VIS is given to the recipient — or the recipient's parent or legal representative — each time a vaccination is administered.

## **WHO** must give out VISs?

**Everyone** who administers vaccines, including both public health professionals and private providers.

## **WHY** must VISs be used?

It's the law. The National Childhood Vaccine Injury Act of 1986 mandates their use. The reason for the law is to ensure that people who are vaccinated are aware of the vaccines' benefits and risks.

## **WHEN** must VISs be given out?

They must be given out at the time of each vaccination — prior to administration of the vaccine.

## **WHICH** VISs must I use?

A VIS must be provided for any vaccine that is covered by the Vaccine Injury Compensation Program (i.e., appears on the Vaccine Injury Table). As of November 2003, VIS's that must be used are: DTaP, Td, MMR, Polio, Hepatitis B, Hib, Varicella, and Pneumococcal Conjugate.\* Other VISs that are available are Influenza (both inactivated and intranasal), Hepatitis A, Pneumococcal Polysaccharide, Meningococcal, Yellow Fever, Rabies, Smallpox, and Anthrax. Their use is not required by the National Childhood Injury Act, but is strongly encouraged – and they must be used when giving vaccines purchased through a CDC contract.

\*Rotavirus is also covered, even though the vaccine is no longer available. Inactivated influenza vaccine is expected to be covered soon.

# **Provider Responsibilities**

## **Providers Should**

- Give the appropriate VIS to the recipient or to the recipient's parent or legal representative with each dose of vaccine. A VIS must be given out prior to administration of the vaccine, and it must be given out each time the vaccine is given.
- Record the following information in the patient's permanent medical record:
  - Which VIS was given
  - Date of publication of the VIS
  - Date the VIS was givenand record the following information in either the patient's permanent medical record or in a permanent office log (the record should be both permanent and accessible):
  - The name, address, and title of the person who administered the vaccine
  - The date of administration
  - The vaccine manufacturer
  - The vaccine lot number
- As needed, supplement VISs orally, with videotapes, with additional printed material, or in any other way that will help recipients understand the disease and vaccine.

## **Providers Should Not**

- Change a VIS or make their own VIS. They should use those developed by CDC.

## **Providers May**

- Add their practice's name, address, or phone number to an existing VIS. If they have a copy on which the publication date was cut off, they may add the date.
- Give out VISs at other times in addition to vaccine administration, (e.g., pre-natal visits).
- Have a recipient or their parent or legal representative sign a separate "informed consent" form if it is required by their state. There is no Federal requirement for written informed consent for vaccinations, and VISs are not informed consent forms, but some states have such requirements.

# Types of VISs and When to Use Them

VISs can be thought of as two types: those for vaccines that are covered by the National Childhood Vaccine Injury Act, and those for vaccines that are not.

In a sense the distinction is artificial, because both types of VIS are used in the same way and they are identical in appearance. However, requirements for their use are different. Also, those covered by the Act bear a reference to the law that requires their use (42 U.S.C. § 300aa-26) and contain information about the National Vaccine Injury Compensation Program, while those not covered by the Act do not.

## Vaccines Covered by the National Childhood Vaccine Injury Act:

Vaccines containing any of these antigens are covered by the National Childhood Vaccine Injury Act:

Tetanus	Measles	Varicella	Hepatitis B
Pertussis	Mumps	Pneumococcal Conjugate	
Polio	Rubella	<i>Haemophilus influenzae</i> type B	
<small>(As of November 2003, Influenza vaccine has been recommended for routine use among children 6-23 months of age by the ACIP, but is not yet covered by the Injury Compensation Program.)</small>			

These VISs must always be used. Every time one of these vaccines is given — regardless of what combination it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — regardless of the age of the recipient — the appropriate VIS must be given out at the time of the vaccination.

VISs in this category (as of November, 2003), and their edition dates, are:

**DTaP** (includes DT): 7/30/01

**Td**: 6/10/94

**MMR**: 1/15/03

**Polio**: 1/1/00

**Hib**: 12/16/98

**Hepatitis B**: 7/11/01

**Varicella**: 12/16/98

**Pneumococcal Conjugate**: 9/30/02

**Note:** When giving combination vaccines for which no separate VIS exists (e.g., Pediarix, Comvax), give out all relevant VISs for the component vaccines.

## Vaccines NOT Covered by the National Childhood Vaccine Injury Act:

VISs exist for several vaccines not covered by the Act. *These VISs must be used when the vaccine given has been purchased under CDC contract.* The legal basis for this is not the Vaccine Injury Act, but the "Duty to Warn" clause in CDC's vaccine contracts.

VISs in this category (as of November, 2003), and their edition dates, are:

**Influenza (Inactivated)**: 5/6/03 **(Live intranasal)**: 9/4/03 (both updated annually)

**Hepatitis A**: 8/25/98

**Yellow Fever**: 3/14/03

**Pneumococcal Polysaccharide**: 7/29/97

**Rabies**: 11/4/03

**Meningococcal**: 7/28/03

**Smallpox**: 1/16/03

**Anthrax**: 4/24/03

# How to Get VISs

- **The Internet.** VISs are available on the internet at three websites. For all VISs except smallpox, go to the National Immunization Program ([www.cdc.gov/nip/publications/VIS/default.htm](http://www.cdc.gov/nip/publications/VIS/default.htm)) or the Immunization Action Coalition ([www.immunize.org/vis/index.htm](http://www.immunize.org/vis/index.htm)).

For smallpox, go to [www.bt.cdc.gov/agent/smallpox/vaccination/infopacket.asp](http://www.bt.cdc.gov/agent/smallpox/vaccination/infopacket.asp)

*These sites will contain the current versions of all VISs.*

All VISs can be downloaded as .pdf documents, which can then be printed out and used as camera-ready copy. If you encounter problems:

- Make sure you have Adobe Acrobat Reader 3.01 or later. Version 3.0 has some printing problems that were corrected in 3.01.
- Download the file directly to disk by holding down the shift key when you click on the link to the .pdf file. Save the file to disk and then open Acrobat Reader and print the file.
- Print one page at a time. If your printer is limited in memory, this can help.

You can also order single hard copies of the VISs using NIP's Online Order Form (at [www.cdc.gov/nip/publications/](http://www.cdc.gov/nip/publications/)).

- **State Health Department.** CDC sends each state health department's immunization program camera-ready copies when a new VIS is published. The immunization program can in turn provide copies to providers within the state.
- **National Immunization Information Hotline.** Call 1-800-232-2522 (English) or 1-800-232-0233 (Spanish).
- **CDC's "Fax-Back" System.** Anyone wanting a single copy of a VIS can get it through the CDC Fax-Back system. Call 1-888-232-3299 (1-888-CDC-FAXX) and, when prompted, enter document number 000002. An NIP "Directory" will be faxed to you, which lists VISs, as well as other NIP documents.

## TRANSLATIONS

VISs have been translated into 29 languages by the California and Minnesota immunization programs. Not all VISs are currently available in all languages:

Arabic	French	Japanese	Punjabi	Spanish
Armenian	German	Korean	Romanian	Tagalog
Cambodian	Haitian Creole	Laotian	Russian	Thai
Chinese	Hindi	Marshallese	Samoan	Turkish
Croatian (Serbian)	Hmong	Polish	Serbo-Croatian	Vietnamese
Farsi	Ilokano	Portuguese	Somali	

You can find these translations on the Immunization Action Coalition website at [www.immunize.org/vis/index.htm](http://www.immunize.org/vis/index.htm). For more information, call California at (510) 540-2065 or Minnesota at (612) 676-5237. Languages are periodically added.

A set of 7 videotapes of VISs (MMR, DTP, Polio, Hepatitis B, Hib, Varicella, and Pneumococcal Conjugate) is available in Spanish from the University of Michigan. Tapes run approximately 5-9 minutes each, and a set costs \$25. For information, call (517) 353-2596.

# Questions and Answers

**Q Should the VISs be used for adults getting vaccines as well as for children?**

**A** Yes. Under the National Childhood Vaccine Injury Act, anyone receiving a covered vaccine should be given the appropriate VIS. VISs are worded so they may be used by adults as well as children. The one exception is the DTaP VIS, since pertussis vaccine is not licensed for adults. There is a separate VIS for adult Td vaccine.

**Q Are VISs "informed consent" forms?**

**A** No. People sometimes use the term "informed consent" loosely when referring to VISs. But even when vaccine information materials had tear-off sheets for parents to sign, they were not technically informed consent forms. The signature was simply to confirm that the "Duty to Warn" clause in the vaccine contract was being fulfilled.

*There is no Federal requirement for informed consent.* VISs are written to fulfill the information requirements of the NCVIA. But because they cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed. Some states have informed consent laws, covering either procedural requirements (e.g., whether consent may be oral or must be written) or substantive requirements (e.g., types of information required). Check your state medical consent law to determine if there are any specific informed consent requirements relating to immunization. VISs *can* be used for informed consent as long as they conform to the appropriate state laws.

**Q The law states that vaccine information materials be given to a child's legal representatives. How is "legal representative" defined?**

**A** A "legal representative" is a parent or other individual who is qualified *under state law* to consent to the immunization of a minor. There is not an overriding Federal definition.

**Q Must the patient, parent, or legal representative physically take away a copy of each VIS, or can we simply let them read a copy and make sure they understand it?**

**A** Ideally the person getting the shot, or their representative, should actually take each VIS home. They contain information that may be needed later (e.g., the recommended vaccine schedule, information about what to do in the case of an adverse reaction). Patients may choose not to take the VIS, but the provider should offer them the opportunity to do so.

**Q When do providers have to start using a new VIS?**

**A** The date for a new VISs required use is announced when the final draft is published in the Federal Register. Ideally, providers will begin using a new VIS immediately, particularly if the vaccine's contraindications or adverse event profile have changed significantly since the previous version.

**Q How should we comply with the law for patients who cannot read the VISs (e.g., those who are illiterate or blind)?**

**A** The NCVIA requires providers to supplement the VISs with "visual presentations" or oral "explanations" as needed. If patients are unable to read the VISs, it is up to the provider to ensure that they have that information. VISs can be read to these patients, or videotapes can be used as supplements. At least one CD-ROM is being produced on which users can hear the VIS's read. Versions of VISs that are compatible with screen reader devices are available on the NIP website.

**Q Why are the dates on some of the VISs so old? Are they obsolete? Why can't they be updated every year?**

**A** VISs are updated only when they need to be. For instance, a VIS would be updated if there were a change in ACIP recommendations that affects the vaccine's adverse event profile, indications, or contraindications. It's true that some people might be concerned that a VIS that is several years old might be outdated. On the other hand, knowing that VISs posted on the NIP website will always be the current versions should help alleviate that concern. Annually changing the dates on VISs that haven't changed otherwise could be confusing too, because there would be multiple VISs in circulation that were identical but would have different dates.

**Q Sometimes a VIS will contain a recommendation that is at odds with the manufacturer's package insert. Why?**

**A** VISs are based on the ACIP's recommendations, which occasionally differ from those made by the manufacturer. These differences may involve adverse events. Package inserts generally tend to include all adverse events that were temporally associated with a vaccine during clinical trials, whereas ACIP tends to recognize only those likely to be causally linked to the vaccine.

**Q What is the reading level of VISs?**

**A** Defining the readability of a VIS by a traditional "grade level" measure can be difficult and misleading. Two of the criteria used by standard readability formulas are word length and sentence length. Word length is not necessarily a reliable measure of readability, as there are multi-syllable words that are widely understood (e.g., "individual") and short words that are not (e.g., "spiv"). VISs are often unavoidably saddled with long words ("*Haemophilus influenzae*" for instance, or "vaccination" or "compensation" or "polysaccharide") which drive the reading level up. Sentence length can be a problem with VISs because they incorporate bulleted lists, which may be read as very long sentences (no period), while they are actually quite easy to understand.

Applying a Fletch-Kincaid test to a VIS usually reveals about a 10th grade reading level, but this should be taken with the caveats in the preceeding paragraph.

In what may be a more useful measure of readability, several VISs were the subject of a series of focus groups among low-literacy parents in a variety of racial and ethnic groups (some not native English speakers) in 1998, and the participants overwhelmingly rated them easy to read and understand.

**Q** How should we distribute VISs when the parent or legal representative of a minor is not present at the time the vaccination is given, for example during a school-based adolescent vaccination program?

**A** CDC's legal advisors have proposed two alternatives for this situation:

**1. Consent Prior to Administration of Each Dose of a Series.** With this alternative the VIS must be mailed or sent home with the student around the time of administration of each dose. Only those children for whom a signed consent is returned may be vaccinated. The program must place the signed consent in the patient's medical record.

**2. Single Signature for Series.** This alternative is permissible only in those States where a single consent to an entire vaccination series is allowed under State law and in those schools where such a policy would be acceptable. The first dose of vaccine may be administered only after the parent or legal representative receives a copy of the VIS and signs and returns a statement that a) acknowledges receipt of the VIS and provides permission for their child to be vaccinated with the complete series of the vaccine (if possible, list the approximate dates of future doses); and b) acknowledges their acceptance of the following process regarding administration of additional doses:

- prior to administration of each dose following the initial dose, a copy of the VIS will be mailed to the parent (or legal representative) who signs the original consent at the address they provide on this statement, or the VIS will be sent home with the student; and
- the vaccine information statements for the additional doses will be accompanied by a statement notifying the parent that, based on their earlier permission, the next dose will be administered to their child (state the date), unless the parent returns a portion of this statement by mail to an address provided, to arrive prior to the intended vaccination date, in which the parent withdraws permission for the child to receive the remaining doses.

The program must maintain the original consent signature and any additional dose veto statements in the patient's medical record. A record must be kept of the dates prior to additional doses that the VIS was mailed, or sent home with the adolescent.

Prior to administration of each additional dose, the provider should ask the adolescent whether he/she experienced any significant adverse events following receipt of earlier doses. If yes, the provider should consider consulting the parent or delaying the vaccination. The adolescent's response to questions about adverse reactions to previous doses should be kept in the medical record.

# **National Childhood Vaccine Injury Act**

(Development, Content, and Use of VISs)

## **42 § 300aa-26. Vaccine Information**

### **(a) General Rule**

Not later than 1 year after the effective date of this subpart, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

### **(b) Development and Revision of Materials**

Such materials shall be developed or revised—

- (1) after notice to the public and 60 days of comment thereon, and
- (2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

### **(c) Information Requirements**

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—

- (1) a concise description of the benefits of the vaccine,
- (2) a concise description of the risks associated with the vaccine,
- (3) a statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) such other relevant information as may be determined by the Secretary.

### **(d) Health Care Provider Duties**

On and after a date determined by the Secretary which is—

- (1) after the Secretary develops the information materials required by subsection (a) of this section, and
- (2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a) of this section, supplemented with visual presentation or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

# **National Childhood Vaccine Injury Act**

## **(Recording Patient Information & Reporting Adverse Events)**

### **42 § 300aa-25. Recording and Reporting of Information**

#### **(a) General Rule**

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in each person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

- (1) the date of administration of the vaccine,
- (2) the vaccine manufacturer and lot number of the vaccine,
- (3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and
- (4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

#### **(b) Reporting**

- (1) Each health care provider and vaccine manufacturer shall report to the Secretary—
  - (A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 2114(b) which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,
  - (B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and
  - (C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after the effective date of this part [Effective December 22, 1987]. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of the effective date of this part [December 22, 1987].

#### **(c) Release of Information**

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, United States Code, or otherwise, to any person except—

- (A) the person who received the vaccine, or
- (B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such persons relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

# Instructions for the Use of Vaccine Information Statements

## Required Use

### 1. Provide VIS when vaccination is given.

As required under the National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-26), all health care providers in the United States who administer any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), or pneumococcal conjugate vaccine shall, **prior to administration of each dose of the vaccine**, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- to the parent or legal representative\* of any child to whom the provider intends to administer such vaccine, or
- to any adult to whom the provider intends to administer such vaccine.

The materials shall be supplemented with visual presentations or oral explanations, as appropriate.

\*“Legal representative” is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor.

### 2. Record information for each VIS provided.

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided indicating:

- (1) the edition date of the materials distributed and
- (2) the date these materials were provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. § 300aa-25 that all health care providers administering these vaccines must record in the patient's permanent medical record (or in a permanent office log):

- (3) the name, address and title of the individual who administers the vaccine,
- (4) the date of administration and the vaccine manufacturer and
- (5) the lot number of the vaccine used.

## Additional Recommended Use

Health care providers may also want to give parents copies of all vaccine information materials prior to the first visit for immunization, such as at the first well baby visit.

### Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State laws.

### Availability of Copies

Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are also available on the Centers for Disease Control and Prevention's website at <http://www.cdc.gov/nip/publications/VIS>. Copies are available in English and in other languages.

### Current Editions of VISs

Diphtheria, Tetanus, Pertussis (DTaP/DT): 7/30/01  
Tetanus Diphtheria (Td): 6/10/94  
Measles, Mumps, Rubella (MMR): 1/15/03  
Hepatitis B: 7/11/01  
Polio: 1/1/00  
*Haemophilus influenzae* type b: 12/16/98  
Varicella (chickenpox): 12/16/98  
Pneumococcal conjugate: 9/30/02

Reference 42 U.S.C. § 300aa-26

1/15/2003

